K091358

MAY 28 2009

DyAnsys

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of Safe Medical Devices Act (SMDA) 1990 and 21 CFR 807.92.

510(k) Number: TBD

Applicant Information:

Date Prepared: 1st October 2008

Name: DyAnsys, Inc.,
Address: c/o Emery & Howard,
577, Airport Boulevard, Suite 610,
Burlingame, CA 95032
Phone: 650.579.7100
Fax: 650.579.7313

Contact Person: Srini Nageshwar
Phone Number: 408.354.8447
Facsimile Number: 650.579.7313

Device Information:

Classification: Class II
Trade Name: ECScope 100
Common Name: ECG Monitor
Classification Name: Electrocardiograph, CFR 870.2340
Product Code: 74 DPS

Predicate Devices:

a. K Number: K072353,
Model Name: Portable ECScope
Manufacturer – DyAnsys, Inc

b. K Number: K080036,
Model Name: Portable ECSCOPE 12i
Manufacturer – DyAnsys, Inc

c. K Number: K032200
Model Name: ELANO Digital 12 Channel Electrocardiograph
Manufacturer – REMCO ITALIA S.P.A

DyAnsys

Device Description:

ECScope 100 is designed to acquire, display and record ECG signals from surface electrodes. The device consists of two basic components: the processing unit and the patient acquisition module.

ECScope 100 is a multi channel electrocardiograph for the simultaneous acquisition of the 12 ECG leads i.e L1, L2, L3, aVR, aVL, aVf, V1, V2, V3, V4, V5 & V6, featuring Display Unit, alphanumeric keyboard and an option to print the ECG data by transferring the image file to computer through USB key or USB Cable on A4 Sheet Paper or Direct Printing through connected printer.

ECScope 100 can record and store in its Database up to 30 ECG tests. Each ECG test can include patient data, doctor's information and ECG measurements. Stored ECG tests can be printed on the external printer by directly connecting the printer or by transferring data through USB cable/Key using a PC.

Intended Use:

ECScope 100 hand held, battery operated 12 channel electrocardiograph is intended to be used for the diagnosis of cardiovascular system complications. ECScope 100 will acquire and record 12 ECG leads simultaneously.

ECScope 100 is intended to be used by a licensed health care practitioner or under the direct supervision of a licensed health care practitioner in a hospital or health care environment. These measurements are not intended for a specific clinical diagnosis.

The clinical significance of the ECG tracings must be determined by the physician in conjunction with clinician's knowledge of patient, the results of physical examination and other clinical findings.

Comparison to Predicate Device(s):

The ECScope 100 is substantially equivalent to the following predicate devices:

a. K Number: K072353,
Model Name: Portable ECScope
Manufacturer – DyAnsys, Inc

b. K Number: K080036,
Model Name: Portable ECScope 12i
Manufacturer – DyAnsys, Inc

c. K Number: K032200
Model Name: ELANO Digital 12 Channel Electrocardiograph
Manufacturer – REMCO ITALIA S.P.A

K091358

DyAnsys

1. ECScope 100 handheld battery operated Multi channel electrocardiograph is intended to be used for the evaluation of the cardiovascular system. ECScope 100 will acquire and record Multi channel ECG signal. ECScope 100 can store in its database up to 30 ECG signal records. The device features a 10 lead ECG.

2. The ECScope 100 has the same intended use as the legally marketed predicate devices.

3. The ECScope 100 was subjected to safety and performance tests against regulatory standards. Final testing for the product included various performance tests as per ANSI/AAMI EC11: 1991 Guidance Document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2009

DyAnsys, Inc.
c/o Mr. Ned Devine
Sr. Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062

Re: K091358
Trade/Device Name: ECScope 100
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Codes: DPS
Dated: May 6, 2009
Received: May 8, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ___ECScope 100____

Indications for Use:

ECScope 100 hand held, battery operated 12 channel electrocardiograph is intended to be used for the diagnosis of cardiovascular system complications. ECScope 100 will acquire and record 12 ECG leads simultaneously.

ECScope 100 is intended to be used by a licensed health care practitioner or under the direct supervision of a licensed health care practitioner in a hospital or health care environment. These measurements are not intended for a specific clinical diagnosis.

The clinical significance of the ECG tracings must be determined by the physician in conjunction with clinician's knowledge of patient, the results of physical examination and other clinical findings.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE

OF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

K091358

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091358